

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

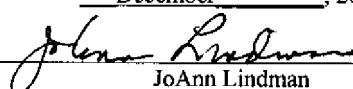
Application No.: 10/601,952 Confirmation No.: 7910  
Applicant : Karl A. Jagger et al.  
Filed : June 23, 2003  
TC/A.U. : 3731  
Examiner : Sonnett, Kathleen C.  
Title: ASYMMETRIC STENT DELIVERY SYSTEM WITH PROXIMAL EDGE PROTECTION AND METHOD OF MANUFACTURE THEREOF  
Docket No. : 1001.2192101  
Customer No. : 11050

**REPLY BRIEF FILED UNDER 37 C.F.R. § 41.41**

Mail Stop Appeal Brief - Patents  
Assistant Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**CERTIFICATE FOR ELECTRONIC TRANSMISSION:** The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 17<sup>th</sup> day of December, 2010

By \_\_\_\_\_

  
JoAnn Lindman

Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellant hereby submits this Reply Brief in furtherance of the Appeal Brief filed July 30, 2010 and in response to the Examiner's Answer of October 20, 2010. No further fees are believed due. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

**I. STATUS OF CLAIMS**

The status of claims is as set forth in the Appeal Brief, to wit:

Claims 1-30 are pending in the application, of which, claims 1-8 and 21-30 are withdrawn.

Claims 9 and 13 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868).

Claim 12 stands finally rejected under 35 U.S.C. §103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Euteneuer et al. (U.S. Patent No. 5,147,302).

Claims 9 and 18 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868).

Claims 10 and 11 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Miraki et al. (U.S. Patent No. 5,704,845).

Claim 12 stands finally rejected under 35 U.S.C. §103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Johnson (WO 02/066095).

Claims 14 and 15 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Motsenbocker et al. (U.S. Patent No. 6,629,350).

Claims 16-17 and 19-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and

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Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Jendersee et al. (U.S. Patent No. 5,836,965).

Claims 9-20 of the application are currently being appealed

## **II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

The Ground of Rejection to be Reviewed on Appeal is as set forth in the Appeal Brief, to wit:

1. Whether claim 9 is patentable under 35 U.S.C. §103(a) as being over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868)?
2. Whether claims 13 and 18 are patentable under 35 U.S.C. §103(a) as being over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868); whether claim 12 is patentable under 35 U.S.C. §103(a) over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Euteneuer et al. (U.S. Patent No. 5,147,302); whether claims 10 and 11 are patentable under 35 U.S.C. §103(a) as over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Miraki et al. (U.S. Patent No. 5,704,845); whether claim 12 is patentable under 35 U.S.C. §103(a) over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Johnson (WO 02/066095); whether claims 14 and 15 are patentable under 35 U.S.C. §103(a) over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Motsenbocker et al. (U.S. Patent No. 6,629,350); and whether claims 16-17 and 19-20 are patentable under 35 U.S.C. §103(a) over Shortt (U.S. Patent No. 6,948,223) in

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view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Jendersee et al. (U.S. Patent No. 5,836,965)?

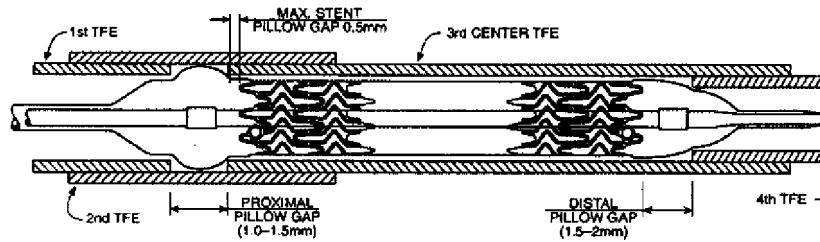
3. Whether claim 11 is patentable under 35 U.S.C. §103(a) over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Miraki et al. (U.S. Patent No. 5,704,845)?

### **III. ARGUMENT**

The remarks in this Arguments section are intended to be read in conjunction with those of the Appeal Brief and are specifically addressed to the points raised in the Response to Arguments section of the Examiner's Answer.

In the Appeal Brief, appellants point out that Shortt does not disclose a separate balloon element and thus does not teach “an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof.” The Examiner, disagrees, writing, “there is no structure in the claim regarding the attachment between the shafts and the balloon that distinguishes the claimed attachment from the prior art of Shortt.” Examiner’s Answer, page 13. On page 14, the Examiner provides a helpful diagram illustrating her position.

Appellants respectfully disagree. In Shortt, the balloon is a part of the outer shaft. Thus the distal end of the outer shaft is distal the balloon, as illustrated in Figure 2 or Figures 7a-c of Shortt. It is the distal end of the outer shaft that is attached to the distal end of the inner shaft.



**FIG. 2 (PRIOR ART)**

Thus Shortt fails to teach the claimed configuration. The distal of the outer shaft of Shortt is not attached to the proximal end of the balloon, and the distal end of the balloon is not attached to the distal end of the inner shaft. One cannot simply assert that the outer shaft ends proximal the balloon, when Shortt clearly shows the outer shaft extending distal of the balloon. Based on the unambiguous teachings of Shortt, Shortt does not disclosed the claimed balloon catheter structure.

The Examiner also disagrees, maintaining that modifying Shortt in view of Morales would have been obvious to one of skill in the art. However, any obvious modification of Shortt in view of Morales would not be the claimed method. Shortt teaches a method of providing a pre-crimped stent and sliding it onto a balloon and then using a mold and heat and pressure to fix the stent to the balloon, creating proximal and distal pillows in the process. Morales teaches a method of crimping a stent to a balloon; no proximal or distal pillows are taught. If one were to crimp the stent on the balloon as taught by Morales, there would be no need to inflate the balloon to fix it to the stent and create the pillows as taught by Shortt.

Further, crimping the stent onto the balloon using the Morales process does reduce the utility of Shortt. Shortt allows for tapered stents and balloons (see Figure 7b), while the process of Morales provides “a uniform and tight crimp.” Morales, col. 3, l. 12-13.

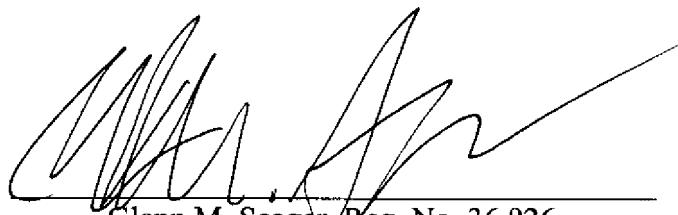
Hanson is relied upon for teaching “that it is known to secure a stent to a balloon using either a proximal and distal pillow...or a proximal pillow only.” Examiner’s Answer, page 15. However, the dams 18, 20 of Hanson are not pillows as taught by Shortt or as would be produced by the claimed method. Hanson teaches, “The distal portion of the catheter may further comprise one or two dams (also referred to as enlarged portions, stops, bumpers, longitudinal motion preventers or the like) and a balloon.” Col. 3, ll. 21-24. The dams are distinct from the balloon, as described by Hanson and as shown in the Figures. For example, Figures 14 and 16 both show the dam as an enlarged portion of the catheter located under the balloon. Hanson teaches crimping the stent to the balloon near one dam or between two dams. Hanson’s teaching regarding the solid dams provides no help regarding the inflatable pillows of Shortt. In any case, if one were to modify Shortt and Morales in view of Hanson, one would replace the inflatable pillows of Shortt with the dams of Hanson.

With regard to the comments regarding claim 11 on page 17 of the Examiner's Answer: Appellants have provided an advantage to the claimed step in the Appeal Brief, which step was in the application as originally filed. There is no requirement that the applicants teach every advantage of their inventive method. On page 17 of the Examiner's Answer, the Examiner hypothesizes that the method of Miraki might provide the same benefits as the claimed method. This is not relevant to whether the cited art renders obvious the claimed invention. Neither Miraki nor the other cited references teach the additional steps of claim 11 of "inserting a protective sleeve over the balloon catheter to a position proximal to the stent and balloon before placing the stent over the balloon, and sliding the protective sleeve over the stent after removing the stepped tube." It is not proper to ignore method steps even when the utility of those steps is difficult to understand or not explained. Nor is suggesting that a different method provides the same utility enough to render the claimed method obvious. Appellants therefore respectfully maintain that claim 11 is not obvious over the cited art.

For the reasons stated above as well as those in the Appeal Brief, claims 9-20 are nonobvious over the cited art, and the Examiner's rejections of claims 9-20 under 35 U.S.C. § 103(a) should be overruled.

Respectfully submitted,

Date: Dec. 17, 2010



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